SEP 15 2009

K092697

510(k) SUMMARY

Submitted By:

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Submission Contact: John D. Tamerius

Date Prepared: September 1, 2009

Device Trade Name: QuickVue® Influenza A+B

Common Name: Influenza Test

Predicate Device: QuickVue Influenza A+B (K031899 and K053146)

Product Code: GNX

Device Classification/Name: 21 CFR 866.3330 / Influenza virus serological reagents.

The device, the QuickVue Influenza A+B test, is similar to other FDA-cleared devices used for the qualitative detection of influenza type A and B directly from clinical specimens. These tests are used to aid in the diagnosis of disease caused by influenza viruses A and B and provide epidemiological information on these diseases (21 CFR 866.3330).

The Food and Drug Administration has classified serological test systems for the detection of influenza virus as Class I.

Intended Use:

The QuickVue Influenza A+B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. Negative results should be confirmed by cell culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

Physiologic Basis of the Test:

Influenza is a highly contagious, acute, viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA viruses known as Influenza Viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with the most serious epidemics. Type B produces a disease that is generally milder than that caused by Type A. Type C has never been connected with a large epidemic of human disease. Both Type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.

Influenza antigens may be detected in clinical specimens by immunoassay. The QuickVue Influenza A+B test is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for influenza antigens. The test is specific to influenza Types A and B antigen with not known cross-reactivity to normal flora or other known respiratory pathogens.

Device Description:

The QuickVue Influenza A+B test, has two Test Line indicators – one for type A and one for type B. The two Test Line indicators allow for the separate identification of type A and type B viral antigens from the same specimen. If either Test Line turns pink-to-red, the test is positive for influenza.

Nasal swabs, nasopharyngeal swabs, nasal wash and/or nasal aspirates serve as specimens for this test. The patient specimen is placed in a tube containing Extraction Reagent, during which time the virus particles in the specimen are disrupted, exposing internal viral antigens. After extraction, the Test Strip is placed in the Extraction Tube for 10 minutes. During this time, the extracted specimen will react with the reagents in the Test Strip.

If the extracted specimen contains influenza Type A and/or B antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the test Strip. If influenza Type A and B viral antigens are not present, or present at very low levels, only a blue procedural Control Line will appear. If no blue procedural Control Line develops, the result is considered invalid.

Device Comparison:

Features	QuickVue Influenza A+B (Proposed)	QuickVue Influenza A+B (K031899 and K053146)
Intended Use	The QuickVue Influenza A+B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. Negative results should be confirmed by cell culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.	The QuickVue Influenza A+B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. The test is not intended to detect influenza C antigens. Negative results should be confirmed by cell culture; they do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.
Specimen Types	Nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens	Nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens
Read Result Time	10 minutes	10 Minutes
Format	Lateral-flow immunoassay	Lateral-flow immunoassay

Device Comparison (cont.):

Features	QuickVue Influenza A+B (Proposed)	QuickVue Influenza A+B (K031899 and K053146)
Detection of Influenza Virus	Detection of Influenza type A and type B	Detection of Influenza type A and type B
Extraction	1 step; buffer and detergent	1 step; buffer and detergent

Summary of Performance Data:

- An analytical study was performed with cultured viruses to determine the analytical sensitivity or minimum detectable level of the QuickVue Influenza A+B for cultured strains of seasonal H1N1 (New Caledonia/20/1999) and 2009 H1N1 (California/04/2009).

Conclusion:

The results of this study show that QuickVue Influenza A+B shows reactivity to the cultured strain of 2009 H1N1 Influenza A virus (California/04/2009) with a minimum detectable level of 1.63 X 10^3 TCID50/ml. Although this test has been shown to detect the 2009 H1N1 virus cultured from a positive human respiratory specimen, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The QuickVue Influenza A+B test can distinguish between influenza A and B viruses, but it can not differentiate influenza subtypes.

The QuickVue Influenza A+B is substantially equivalent with the current QuickVue Influenza A+B test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

SEP 15 2009

John D. Tamerius, PhD.
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Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

Re: k092698
Trade/Device Name: QuickVue Influenza A+B
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: September 1, 2009
Received: September 2, 2009

Dear Dr. Tamerius:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

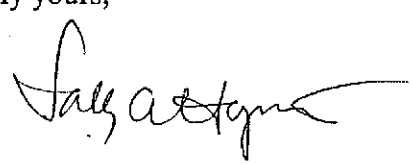
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092698

Device Name: **QuickVue® Influenza A+B test**

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K092698